REMARKS

Claims 1 and 4-12 are pending. Claims 4 and 5 have been withdrawn from consideration.

Applicants have noted that the examiner in charge of the present application at the U.S. PTO has changed. The undersigned thanks Examiner Ouspenskii for consideration and courtesy extended during the telephone interview of December 18, 2008.

In the Office Action mailed February 17, 2009, the Examiner required Applicants to provide a detailed statement regarding public use or sale of product(s) covered by the claims of the present patent application. Applicants acknowledge with thanks Examiner's indication that claim amendments introduced previously are in compliance with the New Matter requirements. Claims 1 and 6-12 have been rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. Claims 1, 7, and 10-12 have been rejected as allegedly anticipated under 35 U.S.C. § 102(a) over WO 01/97842 ("the '842 publication").

By this Amendment, Applicants amended claims 1 and 12. Applicants respectfully request reconsideration and allowance of all pending claims in view of the amendments and remarks set forth below.

I. APPLICANTS DECLARE ABSENSE OF PUBLIC USE OR SALE IN THE UNITED STATES

The Examiner pointed to the demonstration of a product covered the claims at the personal interview held on November 20, 2008. Applicants confirm that the product Anaferon covered by at least one claim of the above-captioned application had been on sale in the Russian Federation.

Attached herewith is a Declaration of Dr. Oleg Epstein ("*Epstein Declaration I*"), the General Director (CEO) of the Materia Medica Holdings. Materia Medica Holdings sells Anaferon in the Russian Federation. The *Epstein Declaration I* is evidence that a) Materia Medica Holdings did not offer Anaferon for sale in the United States within the relevant time period; b) Materia Medica Holdings did not cause Anaferon to be used in public within the relevant time period; and c) Materia Medica did not cause third parties to use Anaferon in public within the relevant time period. While the *Epstein Declaration I* declares the absence of use or sale before January 22, 2005, the inclusion of this date should not constitute an admission that the January 22, 2005 date is of the essence.

It is believed the Examiner's requirement has been met.

II. ANTICIPATION OVER THE '842 PUBLICATION

The Examiner made a new rejection under 35 U.S.C. §102(a) over the '842 publication. According to the Examiner, the '842 application "teach homeopathically potentiated antibodies to gamma interferon (e.g. Example 39 at paragraphs 0345-0347 of US Pat. Pub. No. 2003/0099636), and administration of said antibodies to a patient (ibid.), i.e., a medicament."

Applicants choose not to address the substantive contentions of the Examiner. As demonstrated herein, the '842 publication is not available as prior art against the above-captioned application under 35 U.S.C. §102(a).

The '842 publication was authored by O. Epstein, M. Shtark and T. Kolyadko. The co-inventors of the present patent application are O. Epstein, D. Goldberg, and M. Digay. Attached herein are i) a Declaration of Oleg Epstein ("the *Epstein Declaration II*"), ii) a Declaration of M. Shtark ("the *Shtark Declaration*"), and iii) a Declaration of T. Kolyadko ("the *Kolyadko Declaration*"). All three declarations are un-rebutted evidence that Dr. Epstein was solely responsible for inventing the subject matter of the Example 39 of the '842 publication.

A reference is not available as prior art under 35 U.S.C. §102(a) if the reference describes applicant's own work. MPEP §2132.01; *In re Katz*, 687 F.2d 450 (C.C.P.A. 1982). The showing made in the attached declarations of the co-authors of the '842 publication conclusively remove the '842 publication as prior art.

Withdrawal of the anticipation rejection is respectfully requested.

III. WRITTEN DESCRIPTION REJECTION

The Examiner has rejected the claims as allegedly lacking written description. In the present Amendment, Applicants amended claims 1 and 12 to recite "homeopathically potentised" instead of "homeopathically activated." This amendment was made to bring the claims closer to the precise language in the specification and to address the written description rejection in the most comprehensive manner possible.

In particular, the Examiner has asserted that "the specification does not appear to provide a sufficient written description of the process of homeopathically activating antibodies [*emphasis*

added]." The Examiner continued:

> Applicant's disclosure further appears to rely on the publication of Shvabe W. [citation omitted], cited at page 2, for written description of homeopathic activation. However, the publication does not appear to have been incorporated by reference, and further, "essential material" may not be incorporated by reference.

However, Applicants do not need to rely on incorporation of the Schwabe materials as such. The relevant passage from the specification (at page 2) is set forth below:

> The isolated antibodies to the recombinant human interferon gamma are subjected to consecutive multiple dilutions and to the impact of an external mechanical factor until ultra-low or low doses are obtained, for example, by the homeopathic potentisation procedure (see, W. Schwabe, [rest of citation omitted]). This procedure gives rise to a uniform decrease in the concentration through consecutive dilutions of 1 volumetric part of the initial matter (antibodies) in 9 volumetric parts (for decimal dilution, D) or in 99 volumetric parts (for centimal dilution, C) of a neutral solvent with multiple vertical shaking of each solution; preferably, different containers for each subsequent dilution are used [*emphasis added*].

Therefore, the Schwabe document is not necessary to describe the "homeopathically potentised" form of antibodies: from the written description standpoint, the potentisation procedure is adequately described in the application itself. As an illustration, Example 1 discusses the humoral immune response to "a preparation containing *homeopathically potentised* polyclonal sheep antibodies to murine interferon alpha in a mixture of C12+C30 dilutions [*emphasis added*]." Using the passage from the specification above as a guide, an artisan would clearly know that it would only be necessary to make a C12 dilution (12 centimal dilutions) and mix it with a C30 dilution (30 centimal dilutions) in order to prepare the "homeopathically potentised" form of antibodies of Example 1. This would undoubtedly place the artisan in possession of the invention as required under the law. MPEP § 2163.01, *Vas-Cath v. Maharkar*, 935 F.2d 1555 (Fed. Cir. 1987).

The Schwabe materials were introduced by declaration with the Supplemental Amendment filed on December 10, 2008. These declaration materials were not used to introduce missing matter or to provide written description as such. They were filed only to show that the terms "homeopathically potentised" and C or D (with respect to dilutions) would be clear to an artisan. It is well-established in the law that declarations may be used to address written

description issues if they explain the understandings of one skilled in the art. *Vas-Cath v. Maharkar*, 935 F.2d 1555 (Fed. Cir. 1991). Homeopathy is a well-known, well-established art with its own lexicon and usage. The declaration with the Schwabe materials is evidence that the meaning of the term "potentisation" is so established in the homeopathic art that once the idea of the homeopathic form of antibodies to interferon is conceived and reduced to practice (as it was and as evident from the examples), an artisan would know exactly what it means and how to do it. The Examiner is also respectfully requested to take a note that the rejected claims recite composition of matter, rather than a process of making. Thus, the file wrapper as a whole establish that an artisan would know exactly what "homeopathically potentised" means and would be in full possession of the claimed antibodies based on the application as filed.

The Examiner has cited *Fiers v. Revel*, 25 U.S.P.Q.2d 1601 (Fed. Cir. 1993) and *Regents of University of California v. Eli Lilly*, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997) to support this rejection. These cases involved an entirely different set of facts. For example, in *Eli Lilly*, the applicants had possession only of rat DNA but tried to claim all mammalian DNA without any evidence that respective human DNA would even exist. In contrast, the inventors of the present application have prepared a homeopathic form of antibodies to interferon and claim a homeopathic form of antibodies to interferon. There is little doubt that after the idea of homeopathic form of antibodies is conceived and at least one species of interferon is reduced to practice, the rest of the species within the claims may be envisioned by an artisan and reduced to practice with ease.

Applicants respectfully submit that amended claims 1 and 12 are fully supported in the application as filed.

In view of the foregoing, the Applicants submit that all claims are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. In the event that there are any fees due and owing in connection with this matter, please charge the same to our Deposit Account No. 50-4711.

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/Edward D. Pergament/
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